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SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Device: DSL 10-2800 IGF-I ELISA Kit
Classification Name: Enzyme Linked Immunosorbent Assay, IGF-I
Analyte Name: Insulin-like Growth Factor-I
Regulatory Class: I

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The DSL Active IGF-I ELISA kit was developed for the quantitative measurement of Insulin-like Growth Factor-I in human serum. This ELISA format is a capture assay. Mouse monoclonal antibody to IGF-I is immobilized to the inner surface of the microtitration wells. IGF-I in the standards or samples is "sandwiched" between this monoclonal and the anti-IGF-I antibody conjugated to the enzyme horseradish peroxidase.

The DSL IGF-I ELISA assay is intended for the quantitative determination of IGF-I in human serum. The measurement of serum IGF-I is used as a diagnostic aid in the evaluation of growth-related disorders.

The DSL 10-2800 IGF-I ELISA is substantially equivalent to the DSL 2800 IGF-I IRMA. These kits have the same intended use.

To demonstrate substantial equivalence between the two assays, patient samples ($n = 319$) were collected and assayed simultaneously by both methods. Samples were chosen based on expected IGF-I levels so that samples with low, intermediate and high levels of IGF-I would be evaluated. Linear regression analysis of the results obtained for the comparison with the IGF-I assay gave the equation $Y = 0.63(X) + 0.73$ with a correlation coefficient of $(r) = 0.82$.